



9/27/04

PTO/SB/21 (08-03)

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number

10/767,115

Filing Date

1/28/2004

First Named Inventor

Joshua D. Rabinowitz

Art Unit

Not yet known

Examiner Name

To be assigned

Attorney Docket Number

00029.11CON

### ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert a Provisional Application	<input type="checkbox"/> Proprietary Information
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Remarks		
<p><b>Info. Disc. Statement (2 pp.)</b>  <b>Form 1449 (3 copies, 8 pages each)</b>  <b>Copy of <u>References</u> 173</b>  <b>Return Postcard</b></p>		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name **ALEXZA MDC, 1001 East Meadow Circle, Palo Alto, CA 94303** Customer Number **37485**  
**Elaine C. Stracker, Ph.D., J.D. Telephone (650)-687-3905**

Signature

Date

SEP. 24 2004

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Elaine C. Stracker



PATENT  
Attorney's Docket No.: 00029.11CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Rabinowitz et al.  
Serial No.: 10/767,115  
Filed: 1/28/2004  
Title DELIVERY OF ANTIPSYCHOTICS THROUGH AN INHALATION  
ROUTE

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with their continuing duty of disclosure under 37 CFR §§ §1.97, 1.98 and 1.56, Applicants hereby submit for consideration in the above-identified application the enclosed references. The Information Disclosure statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

For the convenience of the Examiner, the references are listed on a PTO Form 1449 (attached) and copies thereof are enclosed. Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines than an extension and/or other relief is required, Applicants petition for any required relief including any extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 502731**. Please direct all correspondence to the following customer number.

Respectfully submitted,

Date: SEP. 24 2004



Elaine C. Stracker J.D., Ph.D., Reg. 43,166

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Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

SEP 24 2004

PTO/SB/08 (2-92)  
Sheet 1 of 8

Docket Number: 00030.03CON		Application Number: 10/735,198
Applicant: Joshua D. RABINOWITZ et al.		
Filing Date: 12/12/2003		Group Art Unit: Not Yet Known

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	02/02/1971	3,560,607	Hartley et al.			
	2.	05/27/1980	Re. 30,285	Babington			
	3.	08/12/1986	4,605,552	Fritschi			
	4.	01/23/1990	4,895,719	Radhakrishnun et al.			
	5.	09/17/1991	5,049,389	Radhakrishnun			
	6.	08/31/1993	5,240,922	O'Neill			
	7.	02/14/1995	5,388,574	Ingebrethsen			
	8.	08/13/1996	5,544,646	Lloyd et al.			
	9.	12/09/1997	5,694,919	Rubsamen et al.			
	10.	04/07/1998	5,735,263	Rubsamen et al.			
	11.	04/14/1998	5,738,865	Baichwal et al.			
	12.	06/02/1998	5,758,637	Ivri et al.			
	13.	06/16/1998	5,767,117	Moskowitz			
	14.	06/29/1999	5,915,378	Lloyd et al.			
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	16.	09/28/1999	5,957,124	Lloyd et al.			
	17.	10/05/1999	5,960,792	Lloyd et al.			
	18.	11/30/1999	5,993,805	Sutton et al.			
	19.	03/28/2000	6,041,777	Faithfull et al.			
	20.	04/18/2000	6,051,566	Bianco			
	21.	08/01/2000	6,095,153	Kessler et al.			
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	23.	06/05/2001	6,241,969	Saidi et al.			
	24.	07/03/2001	6,255,334	Sands			
	25.	10/23/2001	6,306,431	Zhang et al.			

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<p>Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)</p>				Docket Number: 00030.03CON	Application Number: 10/735,198
				Applicant: Joshua D. RABINOWITZ et al.	
				Filing Date: 12/12/2003	Group Art Unit: Not Yet Known

26.	01/14/2003	6,506,762	Horvath et al.			
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28.	07/15/2003	6,591,839	Meyer et al.			
29.	09/06/2001	US 2001/0020147	Staniforth et al.			
30.	03/14/2002	US 2002/0031480	Peart et al.			
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32.	05/16/2002	US 2002/0058009	Bartus et al.			
33.	07/04/2002	US 2002/0086852	Cantor			
34.	08/22/2002	US 2002/0112723	Schuster et al.			
35.	11/28/2002	US 2002/0176841	Barker et al.			
36.	01/02/2003	US 2003/0004142	Prior et al.			
37.	02/13/2003	US 2003/0032638	Kim et al.			

RELATED ALEXZA MOLECULAR DELIVERY CORPORATION PATENT DOCUMENTS

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39.	08/04/2003	10/633,877	Hale et al.			
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41.	12/30/2003	10/749,539	Rabinowitz et al.			
42.	01/27/2004	10/766,149	Rabinowitz et al.			
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44.	01/27/2004	10/766,566	Rabinowitz et al.			
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46.	01/27/2004	10/766,634	Rabinowitz et al.			
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48.	01/28/2004	10/767,115	Rabinowitz et al.			
49.	01/29/2004	10/768,205	Rabinowitz et al.			
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51.	01/29/2004	10/768,281	Rabinowitz et al.			
52.	01/29/2004	10/768,293	Rabinowitz et al.			
53.	01/30/2004	10/769,046	Rabinowitz et al.			
54.	01/30/2004	10/769,051	Rabinowitz et al.			

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION		Applicant: Joshua D. RABINOWITZ et al.	
(Use several sheets if necessary)		Filing Date: 12/12/2003	Group Art Unit: Not Yet Known

55.	01/29/2004	10/769,157	Rabinowitz et al.			
56.	01/29/2004	10/769,197	Rabinowitz et al.			
57.	02/09/2004	10/775,583	Rabinowitz et al.			
58.	02/09/2004	10/775,586	Rabinowitz et al.			
59.	03/03/2004	10/791,915	Hale et al.			
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65.	03/31/2004	10/813,721	Rabinowitz et al.			
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73.	08/04/2004	10/912,462	Hale et al.			
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76.	11/13/2003	US 2003/0209240	Hale et al.			
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78.	01/09/2003	US 2003/0005924	Rabinowitz et al.			
79.	01/09/2003	US 2003/0005925	Hale et al.			
80.	01/09/2003	US 2003/0007933	Rabinowitz et al.			
81.	01/09/2003	US 2003/0007934	Rabinowitz et al.			
82.	01/16/2003	US 2003/0012737	Rabinowitz et al.			
83.	01/16/2003	US 2003/0012738	Rabinowitz et al.			
84.	1/16/2003	US 2003/0012740	Rabinowitz et al.			

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Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number: 00030.03CON

Application Number: 10/735,198

Applicant: Joshua D. RABINOWITZ et al.

Filing Date: 12/12/2003

Group Art Unit: Not Yet Known

85.	01/23/2003	US 2003/0015189	Rabinowitz et al.			
86.	01/23/2003	US 2003/0015190	Rabinowitz et al.			
87.	01/23/2003	US 2003/0017114	Rabinowitz et al.			
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90.	01/23/2003	US 2003/0017117	Rabinowitz et al.			
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92.	01/23/2003	US 2003/0017119	Rabinowitz et al.			
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95.	01/30/2003	US 2003/0021754	Rabinowitz et al.			
96.	01/30/2003	US 2003/0021755	Hale et al.			
97.	02/20/2003	US 2003/0035776	Hodges et al.			
98.	05/15/2003	US 2003/0091511	Rabinowitz et al.			
99.	05/27/2004	US 2004/010148	Hale et al.			
100.	07/31/2003	US 2003/0138382	Rabinowitz			
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107.	07/01/2004	US 2004/0126326	Rabinowitz et al.			
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112.	08/12/2004	US 2004/0156788	Rabinowitz et al.			
113.	08/12/2004	US 2004/0156789	Rabinowitz et al.			
114.	8/12/2004	US 2004/0156790	Rabinowitz et al.			

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				Applicant: Joshua D. RABINOWITZ et al.			
				Filing Date: 12/12/2003		Group Art Unit: Not Yet Known	

	115.	08/12/2004	US 2004/0156791	Rabinowitz et al.			
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Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES    NO
	116.	03/14/1990	EP 0 358 114	Europe			
	117.	07/03/2001	EP 1 080 720	Europe			
	118.	08/29/2001	EP 0 606 486	Europe			
	119.	04/11/1996	WO 96/09846	WIPO			
	120.	05/09/1996	WO 96/13161	WIPO			
	121.	05/09/1996	WO 96/13290	WIPO			
	122.	05/09/1996	WO 96/13291	WIPO			
	123.	05/09/1996	WO 96/13292	WIPO			
	124.	10/03/1996	WO 96/30068	WIPO			
	125.	08/07/1997	WO 97/27804	WIPO			
	126.	10/09/1997	WO 97/36574	WIPO			
	127.	01/22/1998	WO 98/02186	WIPO			
	128.	05/28/1998	WO 98/22170	WIPO			
	129.	07/23/1998	WO 98/31346	WIPO			
	130.	08/27/1998	WO 98/36651	WIPO			
	131.	09/03/1998	WO 98/37896	WIPO			
	132.	04/08/1999	WO 99/16419	WIPO			
	133.	12/16/1999	WO 99/64094	WIPO			
	134.	01/06/2000	WO 00/00176	WIPO			
	135.	01/06/2000	WO 00/00215	WIPO			
	136.	05/18/2000	WO 00/27363	WIPO			
	137.	05/25/2000	WO 00/29053	WIPO			
	138.	09/17/2000	WO 00/47203	WIPO			

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>		Applicant: Joshua D. RABINOWITZ et al.	
		Filing Date: 12/12/2003	Group Art Unit: Not Yet Known

139.	11/02/2000	WO 00/64940	WIPO			
140.	11/09/2000	WO 00/66084	WIPO			
141.	11/09/2000	WO 00/66206	WIPO			
142.	12/21/2000	WO 00/76673	WIPO			
143.	01/25/2001	WO 01/05459	WIPO			
144.	03/01/2001	WO 01/13957	WIPO			
145.	12/20/2001	WO 01/95903	WIPO			
146.	01/03/2002	WO 02/00198	WIPO			
147.	03/28/2002	WO 02/24158	WIPO			
148..	03/28/2002	WO 02/24158	WIPO			

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*(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	149.	Bennett, R.L. et al. (1981). "Patient-Controlled Analgesia: A New Concept of Postoperative Pain Relief," <i>Annual Surg.</i> 195(6):700-705.
	150.	Carroll, M.E. et al. (1990), "Cocaine-base smoking in rhesus monkeys: reinforcing and physiological effects," <i>Psychopharmacology (Berl)</i> . 102:443-450.
	151.	Clark, A. and Byron, P. (1986). "Dependence of Pulmonary Absorption Kinetics on Aerosol Particle Size," <i>Z. Erkrank.</i> 166:13-24.
	152.	Darquenne, C. et al. (1997). "Aerosol Dispersion in Human Lung: Comparison Between Numerical Simulations and Experiments for Bolus Tests," <i>American Physiological Society</i> . 966-974.
	153.	Davies, C.N. et al. (May 1972). "Breathing of Half-Micron Aerosols," <i>Journal of Applied Physiology</i> . 32(5):591-600.
	154.	Dershwitz, M., M.D., et al. (September 2000). "Pharmacokinetics and Pharmacodynamics of Inhaled versus Intravenous Morphine in Healthy Volunteers," <i>Anesthesiology</i> . 93(3): 619-628.
	155.	Finlay, W.H. (2001). "The Mechanics of Inhaled Pharmaceutical Aerosols", Academic Press: San Diego Formula 2.39. pp.3-14. (Table of Contents). pp. v-viii.
	156.	Gonda,I. (1991). "Particle Deposition in the Human Respiratory Tract," Chapter 176, <u>The Lung: Scientific Foundations</u> . Crystal R.G. and West, J.B. (eds.), Raven Publishers, New York. pp. 2289-2294.

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		Applicant: Joshua D. RABINOWITZ et al.	
		Filing Date: 12/12/2003	Group Art Unit: Not Yet Known

157.	Hatsukami D, et al. (May 1990) "A method for delivery of precise doses of smoked cocaine-base to humans." <i>Pharmacology Biochemistry &amp; Behavior</i> . 36(1):1-7.
158.	Heyder, J. et al. (1986). "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 $\mu\text{m}$ ," <i>J. Aerosol Sci.</i> 17(5):811-822.
159.	Huizer, H., "Analytical studies on illicit heroin. V. Efficacy of volatilization during heroin smoking." <i>Pharmaceutisch Weekblad Scientific Edition</i> (1987). 9(4):203-211.
160.	Hurt, R.D., MD and Robertson, C.R., PhD, (October 1998). "Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial," <i>JAMA</i> 280(13):1173-1181.
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164.	Meng, Y. et al. "Inhalation Studies With Drugs of Abuse," <i>NIDA Research Monograph</i> , (1997) 173:201-224.
165.	Meng, Y., et al. (1999). "Pharmacological effects of methamphetamine and other stimulants via inhalation exposure," <i>Drug and Alcohol Dependence</i> . 53:111-120.
166.	Office Action mailed 8/13/2003 for US application 10/153,313 filed 05/21/2002 "DELIVERY OF BENZODIAZEPINES THROUGH AN INHALATION ROUTE".
167.	Pankow, J.F. et al. (1997). "Conversion of Nicotine in Tobacco Smoke to Its Volatile and Available Free-Base Form Through the Action of Gaseous Ammonia," <i>Environ. Sci. Technol.</i> 31:2428-2433.
168.	Pankow, J. (March 2000). ACS Conference-San Francisco-3/26/00. Chemistry of Tobacco Smoke. pp. 1-8.
169.	Seeman, J. et al. (1999). "The Form of Nicotine in Tobacco. Thermal Transfer of Nicotine and Nicotine Acid Salts to Nicotine in the Gas Phase," <i>J. Agric. Food Chem.</i> 47(12):5133-5145.
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171.	Vapotronics, Inc. (1998) located at <a href="http://www.vapotronics.com.au/banner.htm">http://www.vapotronics.com.au/banner.htm</a> , 11 pages, (visited on June 5, 2000).
172.	Ward, M.E. MD, et al. (December 1997). "Morphine Pharmacokinetics after Pulmonary Administration from a Novel Aerosol Delivery System," <i>Clinical Pharmacology &amp; Therapeutics</i> 62(6):596-609.

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION		Applicant: Joshua D. RABINOWITZ et al.			
<i>(Use several sheets if necessary)</i>		Filing Date: 12/12/2003	Group Art Unit: Not Yet Known		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">173.</td> <td style="width: 90%;">Wood, R.W. et al. (1996). "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity." <i>Pharmacology Biochemistry &amp; Behavior</i>. 55(2):237-248.</td> </tr> </table>				173.	Wood, R.W. et al. (1996). "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity." <i>Pharmacology Biochemistry &amp; Behavior</i> . 55(2):237-248.
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